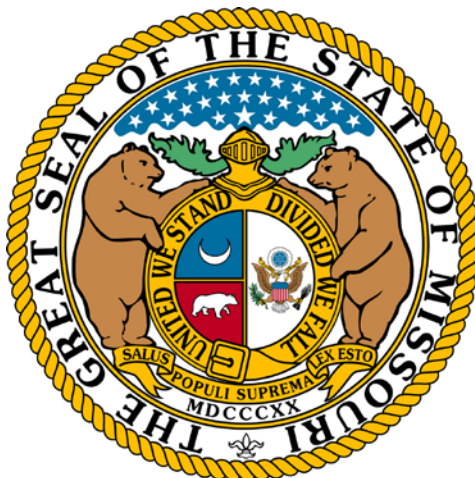


MISSOURI BOARD OF PHARMACY

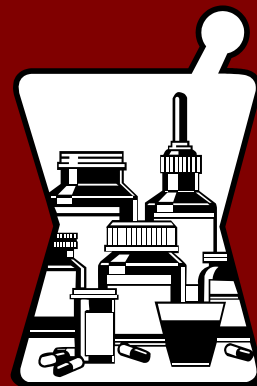


ANNUAL REPORT FY 2016

JEREMIAH W. "JAY" NIXON, GOVERNOR
STATE OF MISSOURI

JOHN HUFF, DIRECTOR
DEPT. OF INSURANCE, FINANCIAL INSTITUTIONS AND
PROFESSIONAL REGISTRATION

KATHLEEN STEELE DANNER, DIRECTOR
DIVISION OF PROFESSIONAL REGISTRATION





Eric R. Greitens
Governor
State of Missouri

Kathleen (Katie) Steele Danner, Acting Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Acting Director

MISSOURI BOARD OF PHARMACY
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Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists
email: MissouriBOP@pr.mo.gov

To The Honorable Governor Eric Greitens:

In compliance with § 338.140.3, RSMO, the Missouri Board of Pharmacy is pleased to submit its Annual Report. The Board of Pharmacy is pleased to report another successful year. This report contains the proceedings of the Board for the fiscal year ending June 30, 2016 ("FY 16").

Respectfully yours,

MISSOURI BOARD OF PHARMACY

By:

A handwritten signature in black ink, appearing to read "K A Grinston", written over a horizontal line.

**Kimberly Grinston
Executive Director**

**DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS
AND PROFESSIONAL REGISTRATION**



DIVISION OF PROFESSIONAL REGISTRATION




Missouri Board of Pharmacy

FY16

BOARD MEMBERS:

CHRISTINA LINDSAY, PHARM.D., PRESIDENT
CHRISTIAN TADRUS, PHARM.D., VICE-PRESIDENT
BARBARA A. BILEK, PHARM.D., MEMBER
DOUGLAS LANG, R.PH., MEMBER
PAMELA MARSHALL, PHARM.D., MEMBER
ANITA K. PARRAN, PUBLIC MEMBER
VACANT POSITIONS (1)



Missouri Board of Pharmacy

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3605 Missouri Boulevard
Jefferson City, Missouri 65102
Phone (573) 751-0091
Fax (573) 526-3464
Web Site <http://www.pr.mo.gov/pharmacists>
Email: MissouriBOP@pr.mo.gov

Kimberly A. Grinston, J.D., Executive Director

TABLE OF CONTENTS

EXECUTIVE SUMMARY.....	2
ABOUT THE BOARD.....	4
BOARD OPERATIONS.....	5
FINANCIAL SUMMARY.....	7
LICENSING.....	9
COMPLAINT HANDLING.....	17
DISCIPLINARY ACTIONS.....	21
INSPECTIONS/INVESTIGATIONS.....	25
COMPOUNDED DRUG TESTING.....	27
RULEMAKING.....	29
BOARD INITIATIVES.....	30

EXECUTIVE SUMMARY

This Annual Report covers the activities of the Missouri Board of Pharmacy from July 1, 2015 to June 30, 2016 (FY16). The Board is pleased to announce another successful regulatory year as reflected below:

Board Operations

- The Board held a total of 20 full Board meetings, including, four (4) regular session meetings, thirteen (13) conference call meetings, three (3) email ballot meetings and twelve (12) Board sterile compounding subcommittee meetings/conference calls. The Board also hosted an additional 13 Working Group and Advisory Committee meetings.
- The Board received/responded to approximately 5,533 telephone calls and increased online services/resources.

Financial Overview

- The Board's total appropriation and authorized transfers for FY16 was \$2,645,128. Of the amount appropriated, the Board expended \$ 2,177,948.11.
- Board revenue increased 23.4%. Expenditures similarly increased 9.88%.
- In compliance with § 338.070, RSMo, the Board lowered renewal fees in FY16 for pharmacies and drug distributors from \$ 450 to \$ 150.

Licensing Summary

- Total licensees/registrants increased from 35,174 licensees/registrants in FY15 to 36,189 licensees/registrants in FY16, representing a moderate 2.9% increase.
- The number of licensed pharmacists increased 5.64% to 10,894 licensees while the number of licensed inactive pharmacists remained consistent.
- Total registered pharmacy technicians remained consistent with a 1% increase to 19,255 technicians.
- Total licensed pharmacies increased a slight 0.22% to 2,636 licensed resident and non-resident pharmacies, representing the lowest pharmacy increase in five (5) fiscal years.
- The total number of licensed drug distributors and drug distributor registrants decreased by 5.57% to 1,474 licensees/registrants. This decrease is consistent with the Board's historical licensing data for non-renewal fiscal years.

Complaint Handling

- The Board received/opened 719 new complaints in FY 16, representing a slight 1% decrease.
- Of the 719 complaints received/opened, 554 complaints were practice-related (77%) while 165 complaints were non-practice related Missouri Department of Revenue tax suspension cases (approx. 23%).

Complaint Dispositions

- The Board closed/issued final dispositions on approximately 689 complaints, including, 174 Department of Revenue tax suspension complaints and 515 non-tax related complaints.

EXECUTIVE SUMMARY

Disciplinary Actions

- The Board issued discipline in approximately 310 cases, representing a 20% decrease in disciplinary actions taken.
- Of the 310 disciplinary actions taken, 136 disciplinary actions were practice related (43.9%) while 174 cases involved non-practice related Department of Revenue tax suspensions (56.1%).

Inspections

- Board inspectors conducted a total of 1,226 inspections of pharmacies and drug distributors. Inspectors/staff also completed 210 investigations.
- Violations were observed or a Compliance Notice was issued in approximately 75% of inspections conducted, which was again consistent with FY15.

Compounded Drug Testing

- In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. 77.1% of products tested in FY16 were satisfactory while 22.9% were unsatisfactory.

Rulemaking

- The Board promulgated the following rules in FY16:
 - 20 CSR 2220-2.020 (Pharmacy Permits)
 - 20 CSR 2220-4.010 (General Fees)
- Additionally, the Board substantively reviewed and opened the following rules for public comment:
 - 20 CSR 2220-2.100 (Collection of Medication for Destruction)
 - 20 CSR 2220-2.200 (Sterile Compounding)

Board Initiatives

- The Board's public strategic planning meeting was held on July 14, 2015. The Board voted to pursue six (6) legislative proposals related to pharmacy practice.
- The Board co-sponsored Missouri's first Joint Regulatory Patient Safety Conference in conjunction with the Missouri Board of Nursing, the Missouri Board of Registration for the Healing Arts and the Missouri Dental Board. The free conference offered a forum for board members and healthcare providers to discuss effective patient safety tools and strategies.





MISSION STATEMENT

The Board's mission is to serve and protect the public by providing an accessible, responsible and accountable regulatory system that:

- *Protects the public from incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty;*
- *Licenses only qualified and competent professionals, and;*
- *Ensures compliance with professional standards and federal and state pharmacy law.*

ABOUT THE MISSOURI BOARD OF PHARMACY

The Missouri Board of Pharmacy was statutorily created in 1909 and has served the citizens of Missouri through the regulation of pharmacy practice for over 100 years. The Board of Pharmacy is an autonomous Board within the Division of Professional Registration, an agency of the Department of Insurance, Financial Institutions and Professional Registration.

MEMBERSHIP

The Board consists of seven (7) members, including, six (6) licensed pharmacists actively engaged in the practice of pharmacy and one (1) public member. By statute, at least one member must provide pharmaceutical services to a hospital, skilled nursing facility or intermediate care facility on a full-time basis. Board members are appointed by the Governor and confirmed by the Missouri Senate. All members hold office for five (5) years from the date of their appointment or until their successors have been appointed and qualified. The Board annually elects a president and vice-president, each of whom serve one (1) year terms.

FUNCTIONS

Pursuant to Chapter 338, RSMo, the Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- Ensuring compliance with Chapter 338, RSMo, and the rules of the Board;
- Licensing/registering pharmacists, pharmacy technicians, intern pharmacists, pharmacies and drug distributors;
- Investigating complaints within the Board's statutory jurisdiction;
- Disciplining licensees which may include, public censure, probation, suspension or revocation of a licensee/registrant;
- Inspection of pharmacies and drug distributors; and
- Approval of preceptors and intern training facilities.

Board Operations

During FY16, the Board held four (4) regular session meetings, thirteen (13) conference call meetings and five (5) email ballot meetings. In addition to Board meetings, the Board established a sterile compounding Board subcommittee in FY16 to review and revise Missouri's sterile compounding requirements. Board members participating on the sterile compounding subcommittee held an additional eleven (11) meetings in FY 16.

The following Board Advisory Committee/Working Group meetings were also held during FY16:

- Hospital Advisory Committee (10 meetings)
- Patient Safety Working Group (2 meetings)
- Pharmacy Technician Working Group (1 meeting)

Staff

The following staff were employed by the Board during FY16:

- **Kimberly Grinston, J.D., Executive Director**
- Tammy Siebert, Administrative Coordinator/Compliance Coordinator**
- Jennifer Luebbert, Compliance Coordinator
- Amber Cundiff, Pharmacist Coordinator
- Laura Henke, Pharmacy/Drug Distributor Coordinator
- Christa Nilges, Senior Office Support Assistant
- Tiffani Stumpf, Pharmacy Technician Coordinator

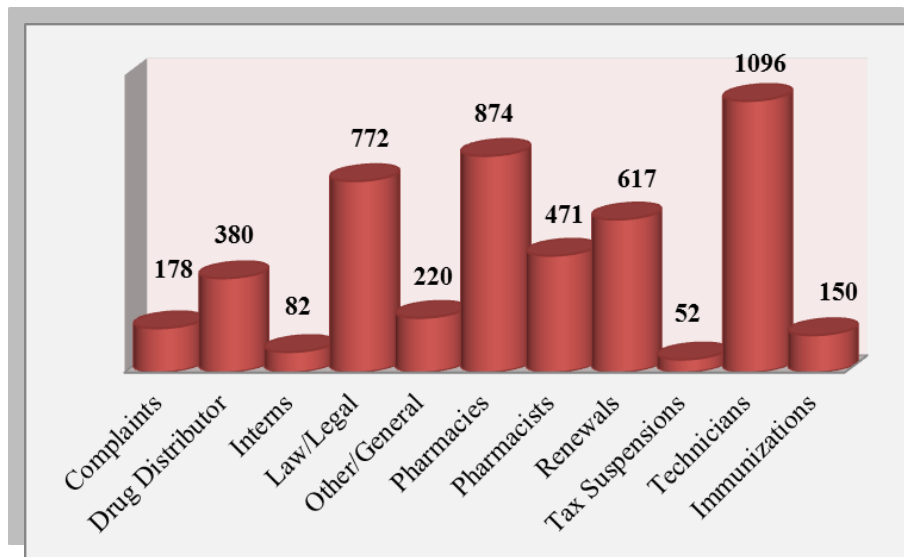
Inspectors

- **Tom Glenski, R.Ph., Chief Inspector**
- Bennie Dean, R.Ph.
- Katie DeBold, PharmD.
- Joe Dino, R.Ph.
- Andrea "Andi" Miller, PharmD.
- Lisa Thompson, R.Ph.
- Daniel Vandersand, R.Ph.
- Frank VanFleet, R.Ph. **
- Elaina Wolzak, R.Ph.
- Barbara Wood, R.Ph.

** Retired in FY16.

Office Activities

- The Board received/responded to 5,533 telephone calls during FY16 representing a 12% decrease in call volume. While call volume decreased, the availability of online services and online compliance resources increased during FY16. Major call topic areas are identified below:

(FY16 Calls by Category)

* Pharmacist category includes licensing, continuing education and audit related questions.

Education/Training

As part of its ongoing efforts to promote voluntary compliance, the Board hosted the following compliance webinars in FY16 (*participants were awarded free continuing education credit*):

- 2015 Legislative/Rule and Regulation Update
- 2015 Review of Multi-Med Pak and Related Automation Regulations
- 2016 Changes to the Board's Inspection Process
- 2016 Bureau of Narcotics and Dangerous Drugs Update
- 2016 Rx: An Ethical Profession

Gold Certificates

The following individuals received Gold Certificates during 2016 representing fifty (50) years of active service as a Missouri licensed pharmacist:

- | | |
|-----------------------------|------------------------|
| ◆ Stephen D. Adams | ◆ David J. Horejsi |
| ◆ Ralph G. Bixler | ◆ James B. Mason, Jr. |
| ◆ Robert E. Brueggeman, Jr. | ◆ Hubert C. McClary |
| ◆ Gary L. Burcham | ◆ Homer L. Ruedin |
| ◆ Vincent J. Deblaze, Jr. | ◆ Lew S. Sanders |
| ◆ Albert D. Durand | ◆ Robert F. Schaefer |
| ◆ James G. Evans | ◆ Alan J. Schneider |
| ◆ Judith H. Evans | ◆ Thomas V. Todd |
| ◆ Robert G. Flynn | ◆ Clifford A. Triplett |
| ◆ Joseph S. Gialde | ◆ Jeffrey S. Wilson |
| ◆ Dale D. Heise | |



Financial Overview

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2016, was as follows:

Personal Service	\$ 1,068,432
Expense and Equipment	\$ 694,930
Criminal History Fund	\$ 5,000
Transfers*	<u>\$ 876,766</u>
	\$ 2,645,128

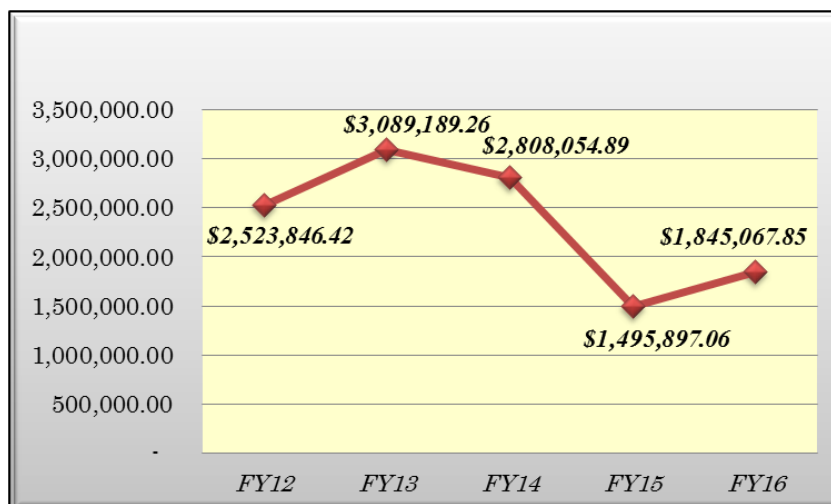
Of the amount appropriated, the Board expended \$ 2,177,948.11 in FY 16 as follows:

Personal Service	\$ 1,007,286.63 (46.25%)
Expense and Equipment	\$ 433,672.29 (19.91%)
Transfers*	\$ 736,989.19 (33.84%)

**Transfers include costs/transfers for rent, the Division of Professional Registration, IT transfers, licensee refunds, attorney general services, Administrative Hearing Commission, DIFP Allocated Expenses and OA Allocated Expenses.*

Revenue Received:

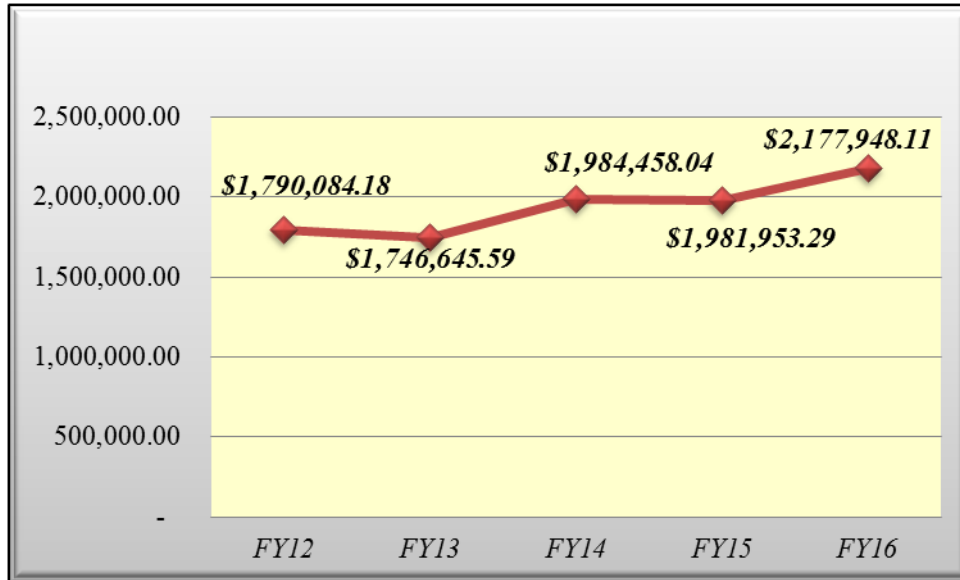
The Board of Pharmacy is statutorily obligated to establish fees as necessary to administer the provisions of Chapter 338, RSMo. Section 338.070, RSMo, provides fees must be appropriate so that the revenue produced does not substantially exceed the cost and expense of administering Chapter 338. In compliance with § 338.070, the Board lowered renewal fees in FY 16 for pharmacies and drug distributors from \$ 450 to \$150. Despite the fee decrease, the Board experienced a 23.3% increase in revenue as reflected below:



The Board has approved an additional fee decrease for pharmacists, interns and technicians that will be effective in FY16 and will continue to monitor revenue increases.

Board Expenditures:

- Board expenditures increased by 9.8% as reflected below:



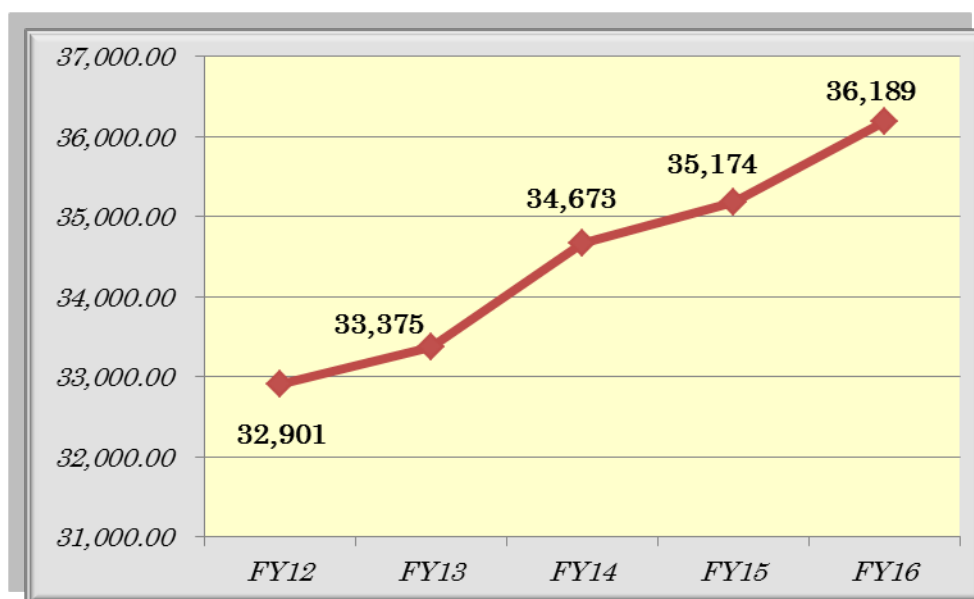
Licensing Summary

Pursuant to Chapter 338, RSMo, the Board licenses and regulates pharmacists, intern pharmacists, pharmacy technicians, pharmacies and drug distributors.

- The Board's total licensee/registrant count increased approximately 2.9% from 35,174 licensees/registrants in FY15 to 36,189 licensees/registrants in FY16.
- The Board's licensing totals at the close of FY16 are provided by classification below:

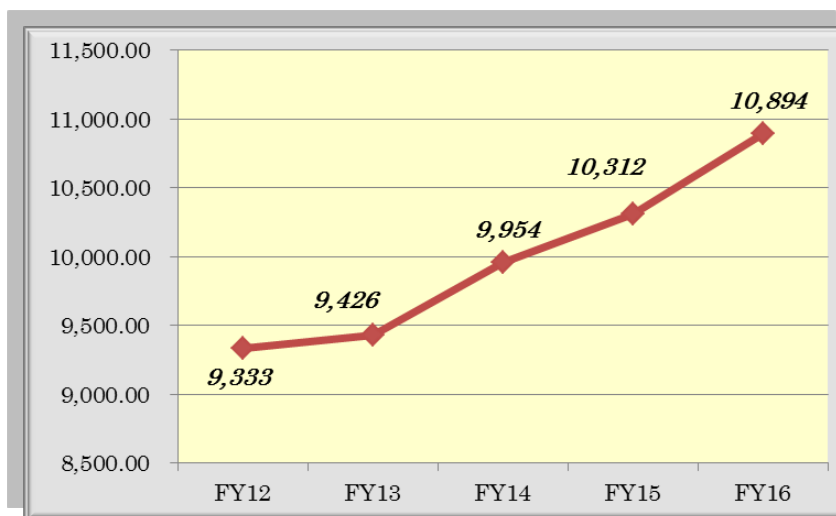
LICENSING TOTALS	
Drug Distributors (licensed & temporary)	1,377
Drug Distributor Manufacturer Registrants	97
Intern Pharmacists	1,930
Pharmacists (active and inactive)	10,894
Pharmacies (instate, non-resident and temporary)	2,636
Pharmacy Technicians	19,255
TOTAL	36,189

Total Licensees/Registrants By Fiscal Year



Pharmacists:

- Total licensed pharmacists (active and inactive) increased 5.64% to 10,894 in FY16 as reflected below:



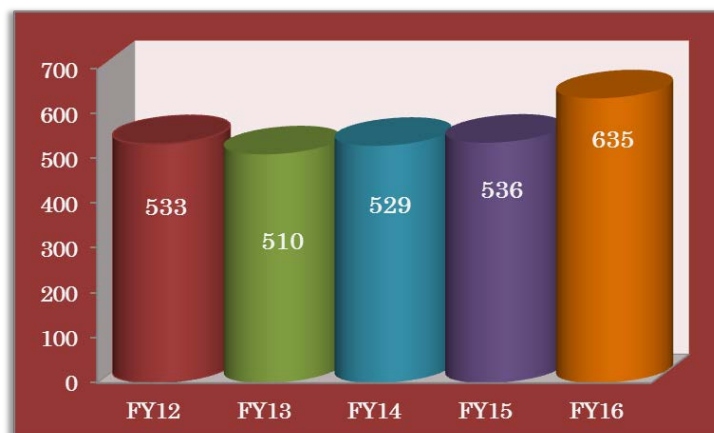
- The total number of active vs. inactive Missouri pharmacists both resident and non-resident are reflected below:

Active Licensees	10,360
Male	5,603
Female	4,757
Inactive Licensees	534
TOTAL LICENSED PHARMACISTS	10,894

*** Inactive pharmacists are not authorized to practice in Missouri but remain licensed.*

Number of New Pharmacist Licenses Issued

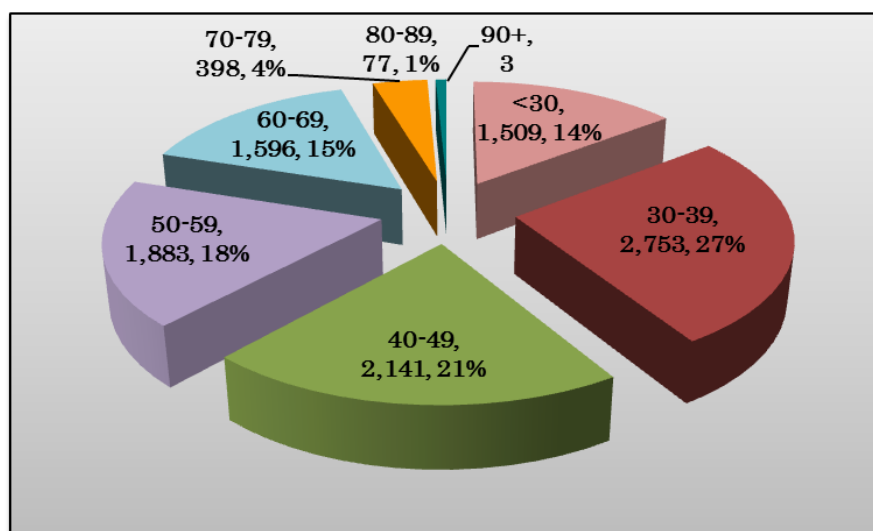
- The number of newly licensed pharmacists increased by 18.4%, representing the largest increase in five (5) fiscal years.



Active Pharmacists By Age Group (Resident and Non-Resident) [#,%]

- No significant changes occurred in the number of active pharmacists categorized by age. Forty-one percent (41%) of licensed Missouri pharmacists are age 39 and under with the remaining fifty-eight percent (58.8%) at age 40 or above.

(Pharmacist Distribution by Age)



Pharmacists Residing in Missouri

- No significant changes occurred in licensed resident vs. non-resident pharmacists in FY16. Approximately 61% of pharmacists licensed by the Board reported a Missouri address as reflected below:

Active Licensees	6,476
Inactive Licensees	205
Total Missouri Resident Pharmacists	6,681

Administration & Immunizations:¹

Pursuant to § 338.010, RSMo, pharmacists are authorized to administer medication by prescription order and to administer vaccines pursuant to a protocol with a Missouri licensed physician, upon filing a *Notification of Intent* with the Board. At the end of calendar year 2016:

- 2,354 pharmacists were authorized to administer medication by prescription.
- 2,654 pharmacists were authorized to administer immunizations by protocol.

Medication Therapy Services:

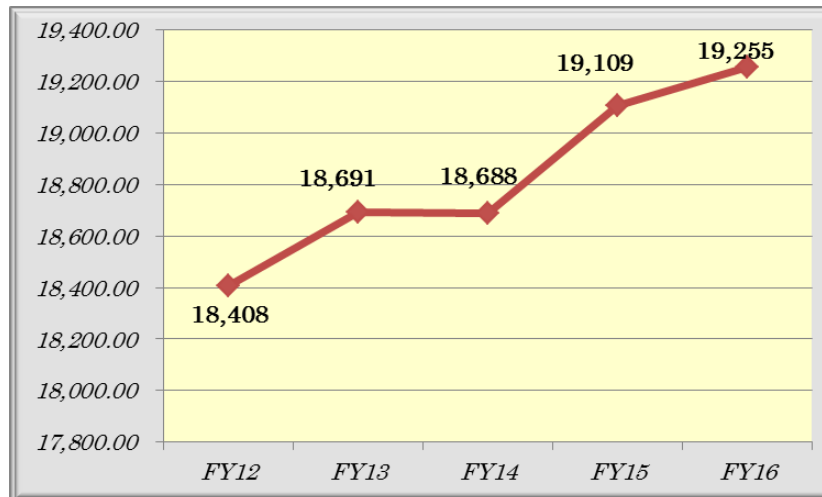
Section 338.010, RSMo, also authorizes the Board to issue a Certificate of Medication Therapeutic Plan Authority (MTS certificate) which allows pharmacists to provide medication therapy services. A total of 2,441 pharmacists held a MT certificate at the end of calendar year 2016 representing a 5.9% decrease from FY 2015.

¹ Due to pending redevelopment of the Division's licensing system, historical data for this category was unavailable at the time of reporting. Reported totals represent data as of the end of calendar year 2016.

Pharmacy Technicians:

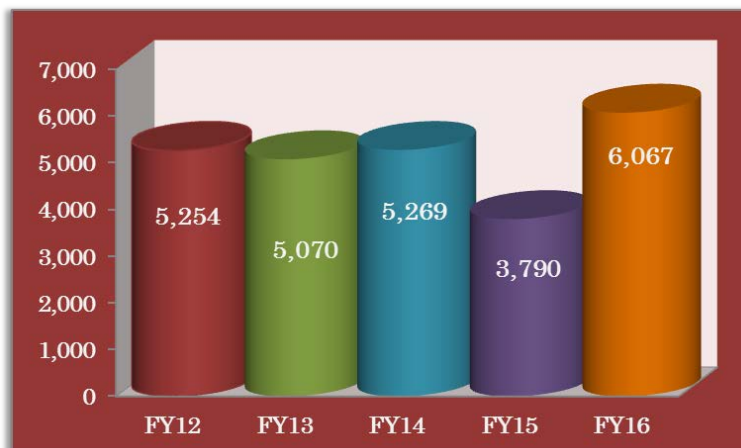
- The number of registered pharmacy technicians remained consistent with less than a 1% increase as reflected below:

(Technician Registrations by FY)



New Pharmacy Technician Registrations Issued

- The percentage of newly registered technicians increased by 60% in FY 16 following a decrease in FY15 likely attributed to vacancies in licensing staff.

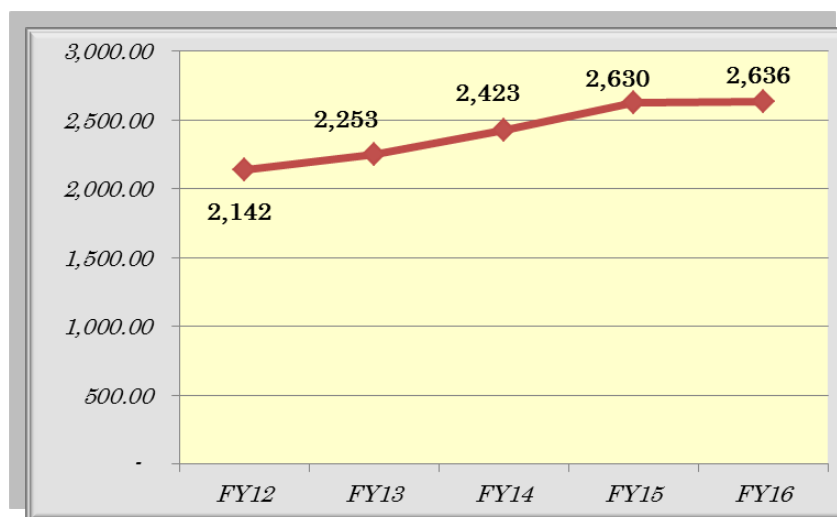


Pharmacy Summary:

- Total licensed pharmacies increased from 2,630 in FY15 to 2,636 pharmacies, representing a minor 0.22% increase. Although the number of pharmacies remained relatively consistent, FY 16 reflected the lowest pharmacy increase in five (5) fiscal years.

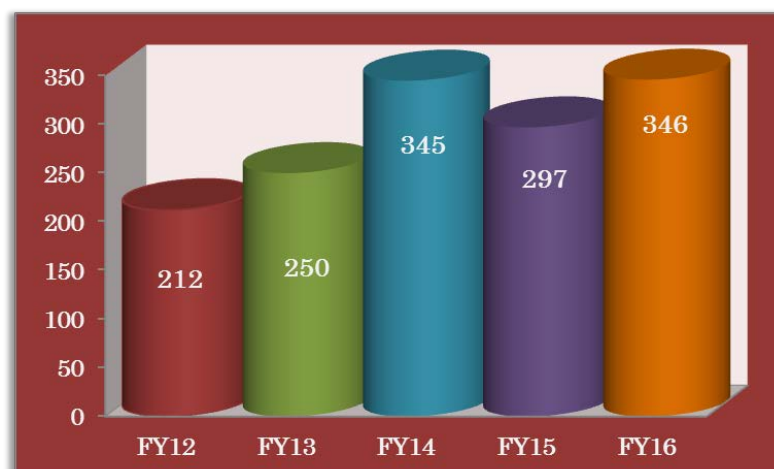
PHARMACY PERMIT TOTALS	
Instate Pharmacies	1,535
Non-Resident Pharmacies	1,101
Temporary Pharmacies	0
TOTAL	2,636

Pharmacy Permitholders By Fiscal Year

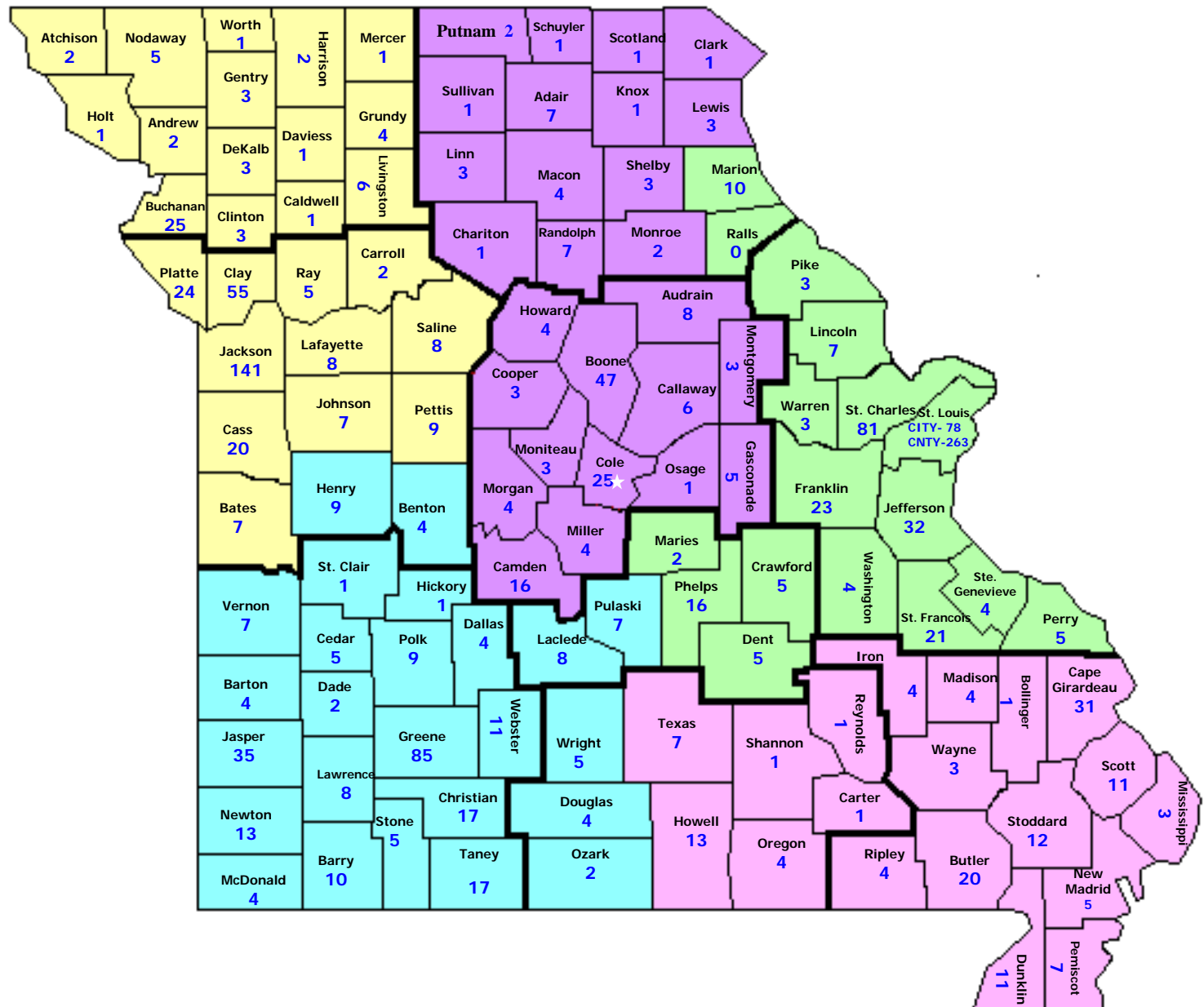


New Pharmacy Permits Issued

- The Board experienced an approximate 16.5% increase in new pharmacy permits issued as follows:



Missouri Pharmacies by County



Statistics to Note:

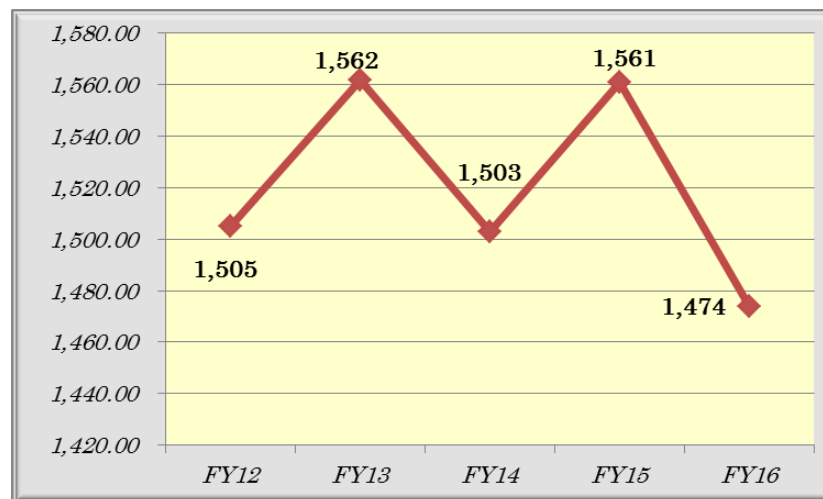
- ◆ Number of counties with 0 pharmacies: 1 (*Ralls County*)
- ◆ Number of counties with ≤ 10 pharmacies: 88
- ◆ Number of counties with 100+ pharmacies: 2 (*St. Louis & Jackson County*)

Drug Distributor Summary:

All in-state drug companies that ship/transfer legend pharmaceuticals or drug-related devices are required to be licensed as a Missouri drug distributor. Additionally, out-of-state drug companies or manufacturers that ship/transfer legend drugs or drug-related devices into Missouri must hold a Missouri drug distributor license.

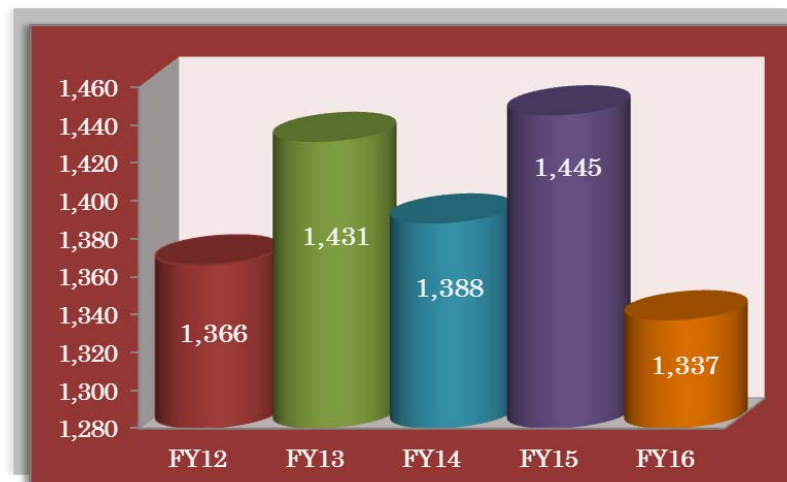
TOTAL DRUG DISTRIBUTORS & DRUG DISTRIBUTOR REGISTRANTS BY FISCAL YEAR

- The total number of licensed drug distributors and drug distributor registrants decreased by 5.57% to 1,474 licensees/registrants (1,377 drug distributors and 97 drug distributor registrants). The Board historically experiences a decline in drug distributors/registrants during a renewal fiscal year as with FY16.



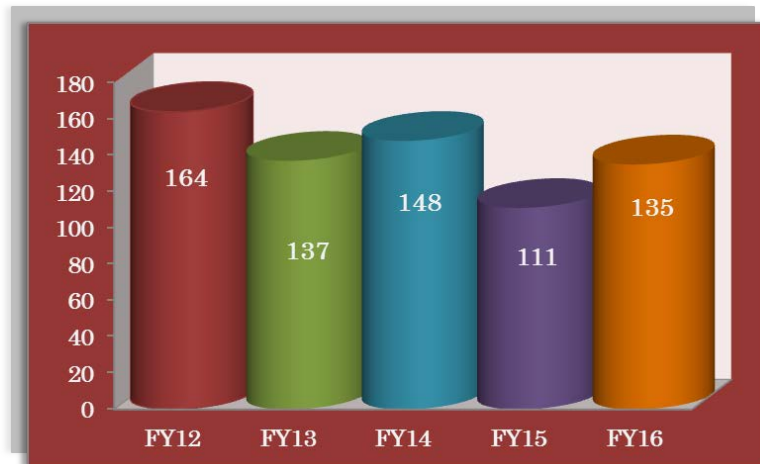
TOTAL DRUG DISTRIBUTORS BY FY

- The number of licensed drug distributors decreased 7% which is once again consistent with historical trends during non-renewal fiscal years.

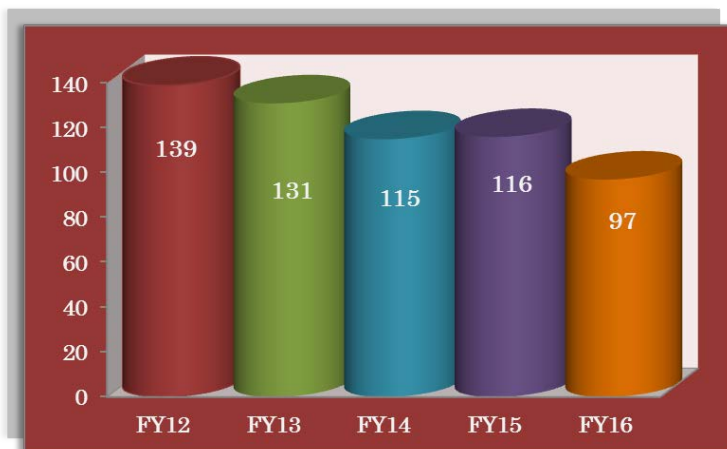


NEW DRUG DISTRIBUTORS LICENSED

- After a 25% decline in FY15, newly licensed drug distributors increased by 26%.

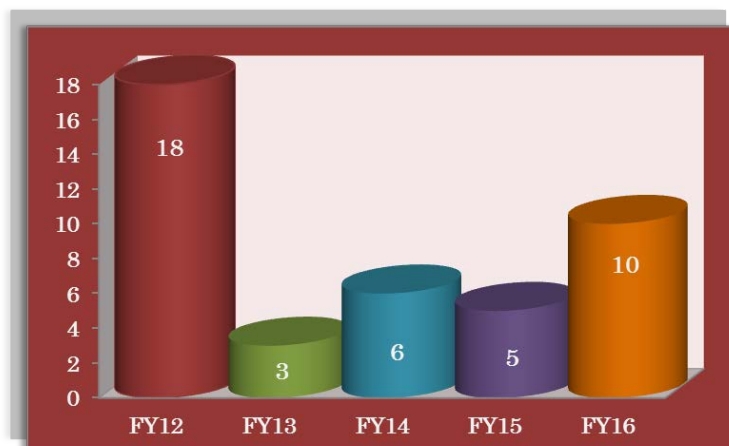


TOTAL DRUG DISTRIBUTOR REGISTRANTS BY FY



NEW DRUG DISTRIBUTOR REGISTRANTS

- While historically lower, the number of drug distributor registrants increased by 50% as reflected below:

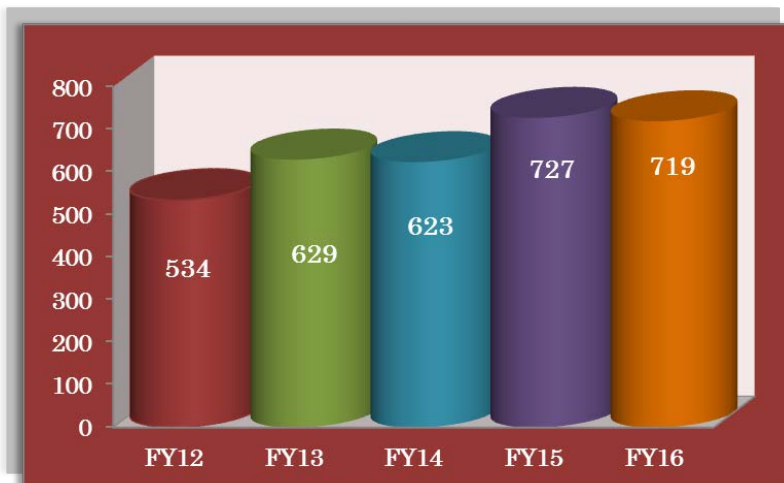


Complaint Summary

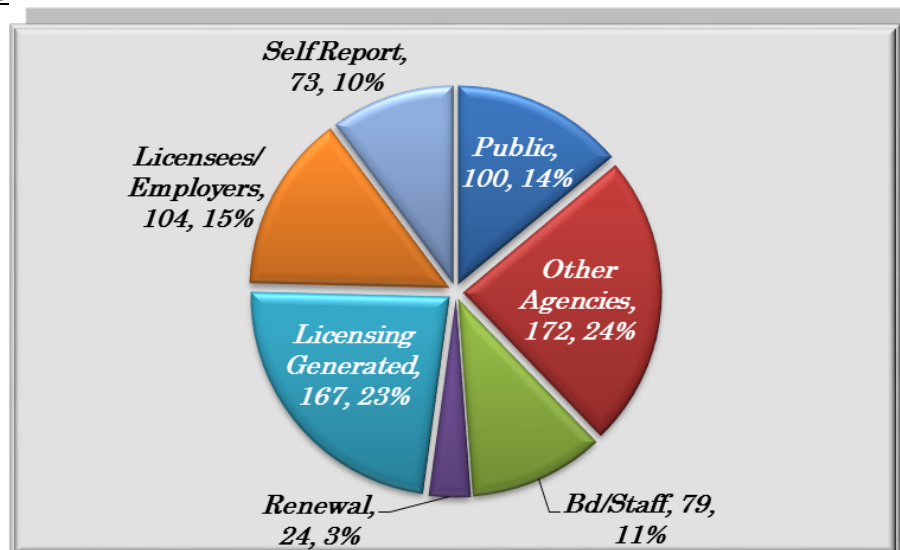
All matters investigated or officially reviewed by the Board are recorded as complaints and processed according to Board procedures. The Board received/opened 719 new complaints in FY 16 representing a slight 1% decrease.

- Of the 719 complaints handled, 554 complaints were practice-related complaints (77%) while 165 complaints were non-practice related Missouri Department of Revenue tax compliance cases (approx. 23%).
- Of the 554 practice related complaints received:
 - 12% involved disciplinary action in another state [68]
 - 8.6% involved dispensing errors [15] or improper dispensing [33]
 - 7% involved drug diversion [9], loss of drugs [12] or theft of drugs [18]
 - 6.3% involved immunization/administration [35]
 - 1.6% involved compounding [9]

Complaints Handled by FY



Complaints by Source



COMPLAINT HANDLING

FY16 COMPLAINTS BY CATEGORY

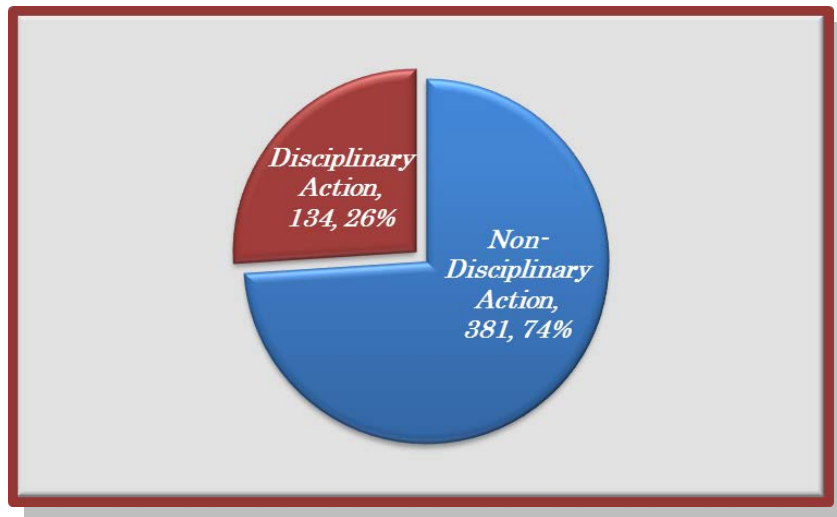
Allowing Unlicensed Person to Practice	3
Audit Findings	4
Compounding	9
Confidentiality	3
Disciplinary Action in Another State	68
Dishonesty	2
Dispensing Error	15
Diversion	9
Drug Distribution Violation	6
Drugs	30
Ethical	2
Expired Drugs in Inventory	1
Felony	9
Fraudulent Prescription	4
Fraud-Unspecified	2
Immunization/Administration	35
Improper Controls	40
Improper Dispensing	33
Incompetence/Failure to Minimum Standards	2
Inspection Violation	1
Insurance Fraud	7
Licensure Applicant	182
Loss of Drugs	12
Misconduct	2
No Jurisdiction	4
Pharmacy Permit Violation	4
Previous Disciplinary Action	2
Recordkeeping	4
Security	1
Substitution	3
Theft of Drugs	18
Theft of Money	11
Unauthorized Dispensing	3
Unlicensed Practice	8
Unprofessional Conduct	12
Unsanitary Pharmacy	1
Unsupervised Dispensing	1
Violation of Disciplinary Order	1
TOTAL	554

HISTORICAL COMPARISONS

	<i>Dispensing Errors</i>	<i>Improper Dispensing</i>	<i>Loss of Drugs</i>	<i>Pharmacy Permit Violations</i>	<i>Practicing w/o License</i>	<i>Diversion/Theft of Drugs</i>
FY 16	15	33	12	4	8	27
FY 15	47	34	6	21	35	30
FY 14	68	15	8	16	28	26
FY 13	52	27	4	20	48	35
FY 12	66	41	4	13	36	31

COMPLAINT DISPOSITIONS

The Board issued final dispositions on approximately 689 complaints in FY16 which included 174 Department of Revenue tax suspension complaints and 515 non-tax related complaints.² The 515 non-tax related complaints were disposed of as follows:

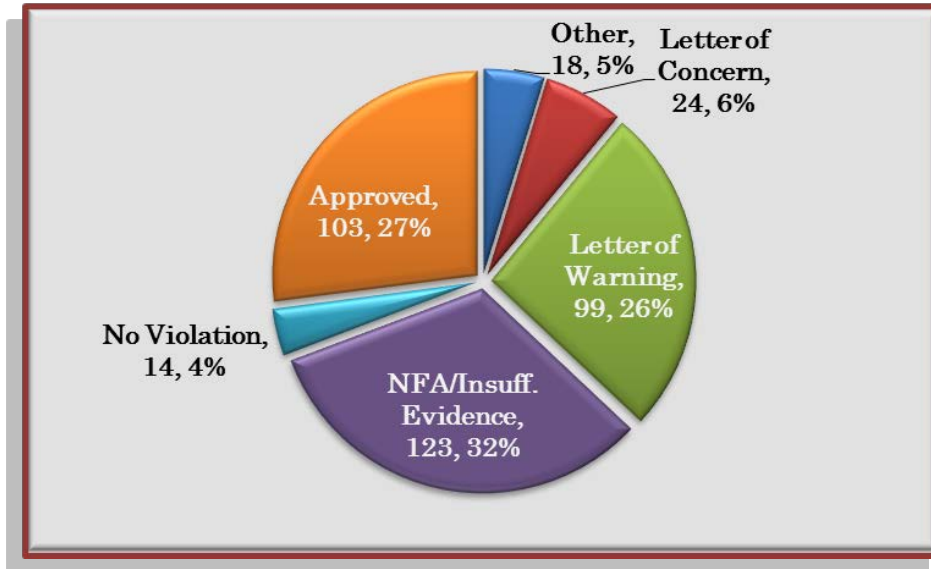
(Non-Tax Related Complaint Dispositions)

The ratio of non-disciplinary actions to disciplinary actions remained consistent from FY15 when 30% of non-tax related complaints were closed with discipline and 70% were closed without disciplinary action. Although the ratio remained consistent, FY16 disciplinary actions decreased by 11.8%.

² The 689 complaint dispositions includes complaints received in prior fiscal years but finally determined in FY15. As a result, the number of complaints disposed of in FY16 will not equal the number of new complaints received.

SUMMARY OF NON-DISCIPLINARY COMPLAINT RESOLUTIONS:

The following action was taken in the 381 non-tax related complaints closed without disciplinary action in FY16: (see *Disciplinary Action* section for complaints closed with disciplinary action)

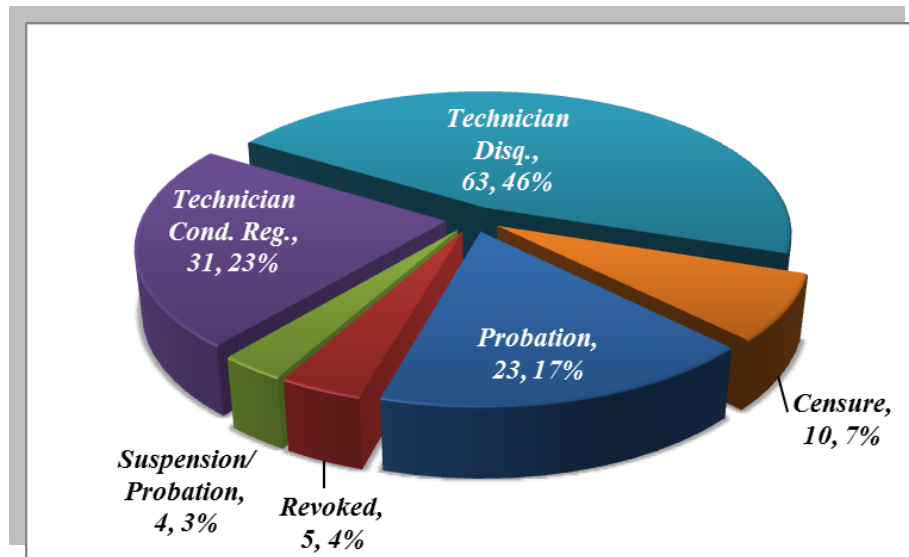


* Other: Non-Administrative Letter [6], Closed But Flagged for Future Review [6], Voluntary Surrender [2], Cease & Desist [1], Denied [1], Misc. [1], Refer to Other Bd. [1],



Summary of Disciplinary Action

- The Board issued disciplinary action in 310 cases in FY16, representing a 20% decrease from FY15. One-hundred and thirty-six (136) practice related disciplinary actions were issued (43.9%) while the remaining 174 cases involved non-practice related Department of Revenue tax suspensions (56.1%).
- The following disciplinary action was taken in the 136 practice-related disciplinary actions issued:



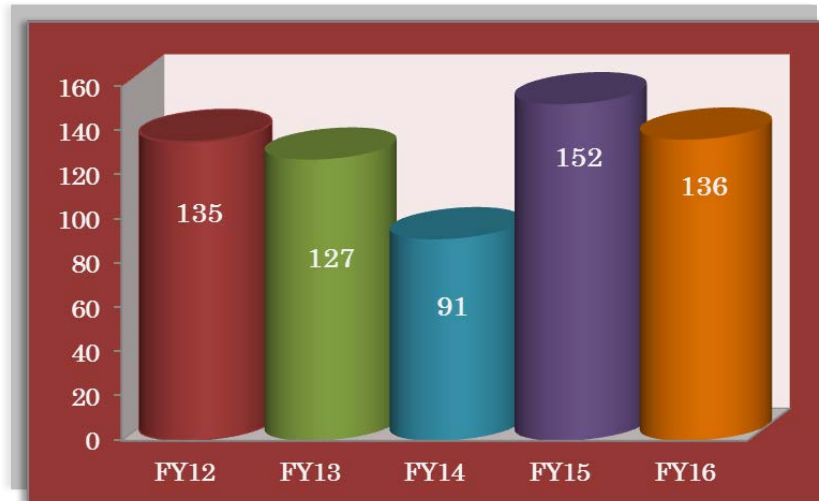
DISCIPLINARY ACTIONS BY CATEGORY

Technician Registrations Suspended under § 324.010 (tax purposes)	174
Technicians Disqualified	63
Technicians Placed on Conditional Employment	31
Pharmacist Licenses Censured	6
Pharmacist Licenses on Probation	14
Pharmacist Licenses Suspended Followed by Probation	4
Pharmacist Licenses Revoked	3
Pharmacy Permits Censured	4
Pharmacy Permits on Probation	8
Pharmacy Permits Revoked	2
Drug Distributor Licenses on Probation	1
TOTAL	310

PRACTICE RELATED DISCIPLINARY ACTIONS *

- Ninety-Four (94) pharmacy technicians, 27 pharmacists, 14 pharmacies and 1 drug distributor were disciplined for practice-related issues during FY16. Total practice related disciplinary actions decreased by 10.5% from FY15 as reflected below:

(Total Practice-Related Disciplinary Actions by FY)

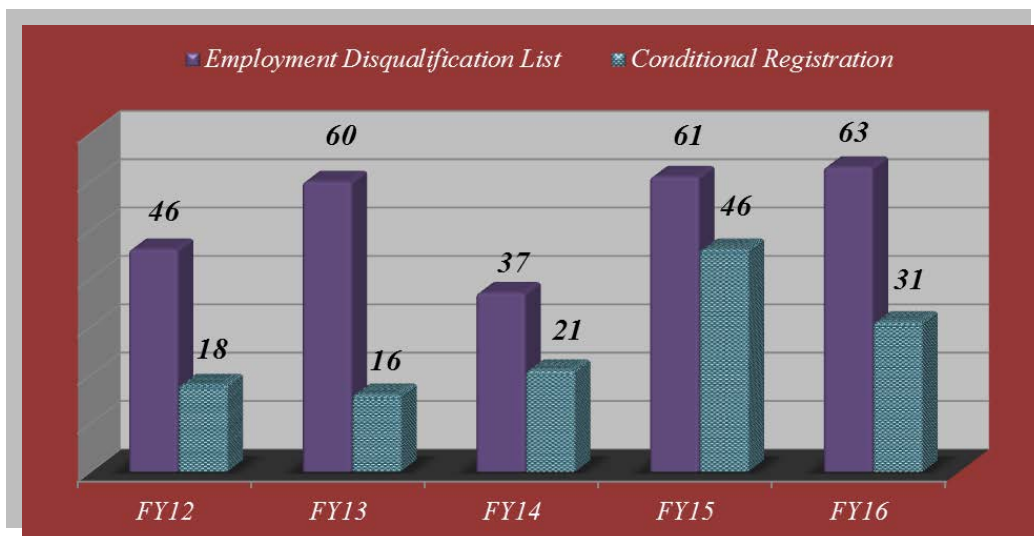


* Does not include tax suspensions pursuant to § 324.010, RSMo.

PHARMACY TECHNICIAN DISCIPLINE

- Approximately 69% of practice related disciplinary actions in FY16 involved pharmacy technicians placed on the Employment Disqualification List or issued a conditional registration pursuant to § 338.013, RSMo. Technician practice-related disciplinary actions remained stable with a minor 3% decrease as reflected below:

(Practice Related Pharmacy Technician Discipline by FY)



DISCIPLINARY ACTIONS

GROUND FORS FOR TECHNICIAN EMPLOYMENT DISQUALIFICATION *(Cause for EDL / # Disciplined)*

- Criminal History (27)
- Diversion (14)
- False Application/Controlled Substance Violations (1)
- Misconduct/Unauthorized Dispensing (3)
- Misconduct/Fraudulent Prescriptions (2)
- Illegal Drug Usage/Positive Drug Test (8)
- Theft (Non-Drug Related) (7)
- Unlicensed activity (Working while suspended/expired) (1)

GROUND FORS FOR TECHNICIAN CONDITIONAL REGISTRATION *(Cause for CR/ # Disciplined)*

- Criminal History (19)
- Diversion (Non-Controlled) (1)
- Prior Disciplinary Action (2)
- Improper/Prior admitted drug use (5)
- Improper/Unauthorized Dispensing (1)
- Misconduct (1)
- Theft (Non-Drug Related) (1)
- Unlicensed activity (Working while suspended/expired) (1)

PHARMACIST DISCIPLINE BY FY:

- Pharmacist discipline increased by 58.8% with 27 pharmacists disciplined for practice-related issues as reflected below:

	FY12	FY13	FY14	FY15	FY16
Censure	8	11	7	5	6
Probation	17	10	6	5	14
Suspension	0	0	0	2	0
Suspension/Probation	9	5	2	4	4
Revocation	2	2	2	1	3
TOTAL	36	28	17	17	27

PHARMACY DISCIPLINE BY FY

- Pharmacy discipline declined 33.3% as follows:

	FY12	FY13	FY14	FY15	FY16
Censure	3	4	2	9	4
Probation	6	9	9	12	8
Revocation	0	1	0	0	2
Voluntary Surrender	2	2	0	0	0
TOTAL	11	16	11	21	14

DISCIPLINARY ACTIONS

DRUG DISTRIBUTOR DISCIPLINE BY FY

	FY12	FY13	FY14	FY15	FY16
Censure	7	0	0	0	0
Probation	4	4	0	3	1
Voluntary Surrender	1	0	0	0	0
TOTAL	12	4	0	3	1

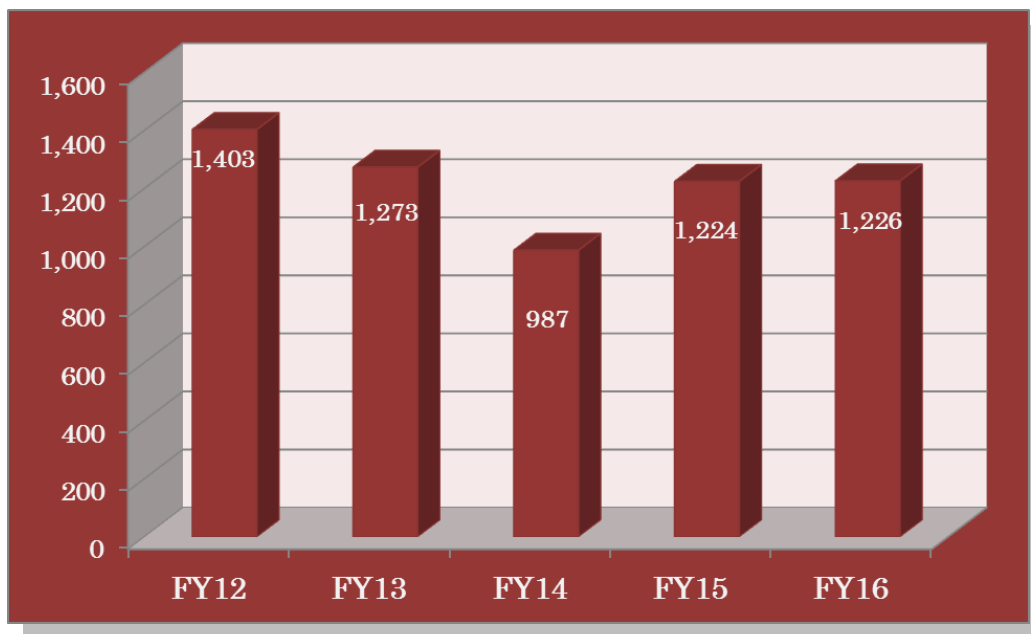


Inspection/Investigation Summary

The Board conducts new and routine inspections of all Missouri located pharmacies and drug distributors. Board inspectors also conduct investigations as assigned.

- Board regulatory inspections remained consistent with a total of 1,226 inspections conducted in FY16 (1,092 pharmacy inspections and 134 drug distributors). Forty-three (43) drug distributors were exempt from inspection pursuant to 20 CSR 2220-5.040 as authorized for facilities inspected by the U.S. Food and Drug Administration.
- The Board continues to inspect all sterile compounding pharmacies annually.
- A total of 210 investigations were completed in FY16 by Board staff/inspectors.

Pharmacy/Drug Distributor Inspection Summary



INSPECTION FINDINGS

At the conclusion of an inspection, the inspector may initiate one of the following resolutions:

- Observation Report: Issued if no compliance issues are identified at the time of inspection or if compliance violations are noted that can generally be corrected and do not require further review/documentation.
- Compliance Notice: Issued if compliance concerns are discovered that require official documentation of corrective measures or in instances of multiple or repeat compliance violations.
- Quality Assurance Report: Issued if there is a specific question regarding the dispensing/handling of a particular prescription and/or drug.
- Investigation: An investigation may be initiated during an inspection if additional factual information may be necessary to assess compliance.

FY16 INSPECTION RESULTS*

- Approximately 75% of Board inspections resulted in violations noted or a compliance notice being issued. Inspection results were consistent with FY15 where 72% of FY15 inspections resulted in compliance notices/violations noted. FY16 inspection results are summarized below:



** Includes inspection results for follow-up inspections and investigations.*



Testing Summary

In 2003, the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxins. The tables listed below are for the fiscal year ending June 30, 2016:

<i>Dosage Form</i>	<i>Tests Performed</i>
<i>Aliquot</i>	2
<i>Capsule</i>	28
<i>I.V. solution</i>	19
<i>Inhalation solution</i>	1
<i>Injection</i>	4
<i>Lollipop</i>	1
<i>Ophthalmic solution</i>	2
<i>Oral solution</i>	1
<i>Oral suspension</i>	6
<i>Topical cream/ointment</i>	7
<i>Troche</i>	9
<i>Vaginal cream</i>	1
<i>Vaginal Suppository</i>	2

<i>Test Results</i>	<i>Tests Performed</i>	<i>Percentage</i>
<i>Satisfactory</i>	64	77.1%
<i>Unsatisfactory</i>	19	22.9%
<i>Total</i>	83	100%

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 37.6% to 155.8%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

<i>Drugs With Unsatisfactory Results</i>
<i>Estradiol/Estriol capsule</i>
<i>Estradiol/Estriol /Progesterone capsule</i>
<i>Estradiol/Estriol /Progesterone/Testosterone capsule</i>
<i>Ceftriaxone I.V. solution</i>
<i>Dicyclomine/Clonidine/Gabapentin/Lidocaine/Pentoxifylline topical cream</i>
<i>Estradiol/Progesterone capsule</i>
<i>Ketoprofen/Cyclobenzaprine/Gabapentin In</i>
<i>Lidocaine/Prilocaine topical cream</i>

*Drugs with Unsatisfactory Results (Cont'd)**Methimazole topical cream**Naltrexone capsule**Ondansetron I.V. solution**Papaverine/Phentolamine Mesylate/Prostaglandin injection**Progesterone troche**Quinacrine HCl capsule**Spiroinolactone oral suspension**Tetracaine lollipop*

Rule Changes

The Board continued to review Missouri's pharmacy rules to ensure appropriate and consistent regulation. The following rules were pending, approved and/or promulgated in FY16:

PROMULGATED RULES

PROMULGATED RULES		
20 CSR 2220-2.020	Pharmacy Permits	Rule revised to accommodate pharmacy dispensing of prescriptions issued by an authorized prescriber based on a legally valid telehealth/telemedicine examination.
20 CSR 2220-4.010	General Fees	Decreased pharmacist, intern and pharmacy technician renewal fees.

APPROVED RULES <i>(Rules approved by the Board / Pending approval for filing)</i>		
20 CSR 2220-2.200	Sterile Pharmaceuticals	Substantially revises Missouri's sterile compounding requirements and enhances patient safety standards.
20 CSR 2220-2.700	Pharmacy Technician Registration	Updates Missouri's technician registration requirements.
20 CSR 2220-6.080	Medication Therapy Services by Protocol	Clarifies existing language and updates rule to accommodate additional practice settings.

The Board also considered and received public comments on the following rules:

- 20 CSR 2220-2.100 (Collection of Medication for Destruction)



Strategic Planning Initiatives

As part of its regulatory mission, the Board holds an annual strategic planning meeting to assess Board operations and review Missouri's regulation of pharmacy practice. The Board's FY16 strategic planning meeting was held on July 14, 2015. As part of strategic planning, the Board voted to pursue the following legislative proposals during the 2015-2016 legislative session:**

- Adverse Reactions: Would amend § 338.010, RSMo, to allow pharmacists to administer emergency medication to treat an adverse reaction after a vaccine or drug administered by a pharmacist.
- Implementation of the Drug Quality and Security Act: Would establish licensing requirements for third-party logistic providers as defined by the federal Drug Quality and Security Act.
- Disciplinary Authority: Would amend § 338.055, RSMo, to include additional grounds for discipline related to pharmacy practice.
- Mandatory Reporting: Would require Board licensees to report adverse licensing actions to the Board.
- Immunizations: Would amend § 338.010, RSMo, to allow immunizations to be administered as authorized by the prescriber.
- Non-Resident Pharmacies & Drug Distributors: Would prohibit non-resident pharmacies and drug distributors from renewing their Missouri license/registration if the entity does not have a valid license in their home state.

*** Legislative proposals must be approved by the Governor prior to submission.*

Patient Safety

The Board continued its campaign to encourage and promote patient safety in pharmacy practice. As part of its ongoing efforts, the Board sponsored/hosted the following in FY16:

- The Board co-sponsored Missouri's second Joint Regulatory Patient Safety Conference in conjunction with the Missouri Board of Nursing, the Missouri Board of Registration for the Healing Arts and the Missouri Dental Board. The free conference offered a forum for board members and healthcare providers to discuss effective patient safety tools and strategies. Presentations were given by patient safety leaders in Missouri and included sessions on enhancing patient communication and enhancing inter-professional communication/collaboration.